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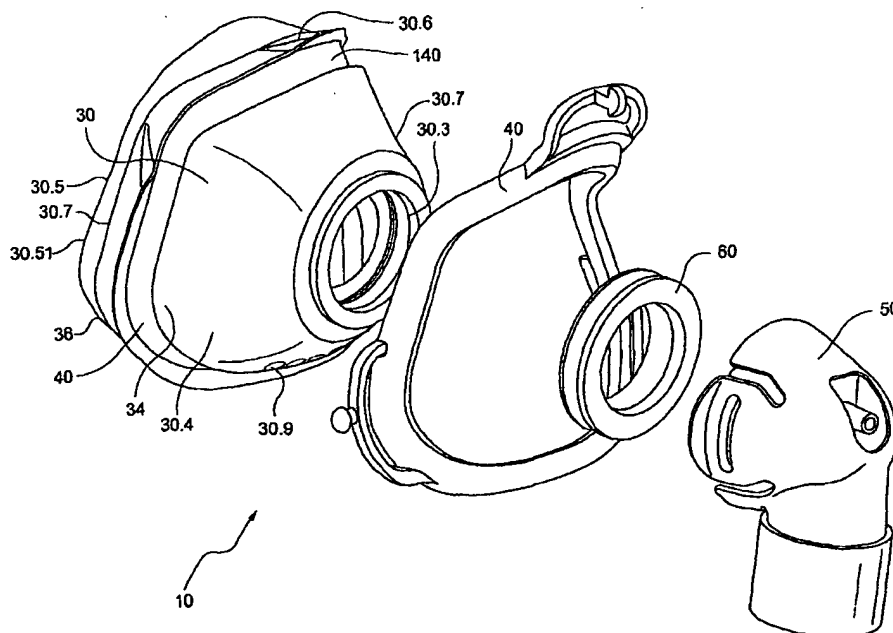
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(54) Title: A MASK SYSTEM



(57) Abstract: The inventions concerns a mask system for treating sleep disordered breathing, comprising headgear (20), a shell/cushion (30) including a channel (524) adjacent a front aperture (30.3), a frame (40), an elbow (50) including at least one undercut (50.2) on a proximal end, a retaining ring (60) including a rear flange (64) adapted to be retainably insertable in the channel (524) of the shell/cushion (30), and a front flange (66) adapted to retainably engage with the at least one undercut (50.2) of the elbow (50).

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**A MASK SYSTEM****FIELD OF THE INVENTION**

[0001] The invention relates to a mask system for use with positive pressure ventilation of sleep disordered breathing. In particular, the invention relates to a low cost mask system.

**BACKGROUND**

[0002] Obstructive Sleep Apnea (OSA) is a condition characterised by repetitive obstruction of the upper airway often resulting in oxygen desaturation and arousals from sleep. The classic daytime manifestation is excessive sleepiness but other symptoms such as unrefreshing sleep, poor concentration and fatigue are commonly reported (Sleep-Related Breathing Disorders in Adults-AASM Task Force, Sleep 22, 1999)

[0003] The use of nasal continuous positive airway pressure (CPAP) to treat OSA was taught by Sullivan in US Patent 4,944,310. Other developments are taught in US Patent 5,704,345; 6,029,665 and 6,363,933.

[0004] Nasal CPAP systems typically comprise a flow generator, air tubing, and a patient interface (for example, a nasal mask). The flow generator provides a supply of air at positive pressure.

[0005] A variety of mask systems are known for use in treating sleep disordered breathing (SDB), such as the BUBBLE® mask, MIRAGE®, ULTRA MIRAGE®, and MIRAGE VISTA™ masks, all manufactured by ResMed Limited.

[0006] Another known mask is the Weinmann nasal mask.

[0007] A mask system typically comprises headgear and a mask assembly. The headgear is used to hold and position the mask on the face of a patient. The mask assembly typically comprises at least a rigid shell and a soft face-contacting cushion. Some mask assemblies also include elbows, vents, headgear clips, forehead supports.

[0008] A number of cushions have been patented, for example see US Patents 6,112,746; 6,357,441; 6,513,526; as have forehead supports (See US Patents 6,119,693; 6,463,931; 6,520,182; 6,532,961), headgear connectors (US Patent 6,374,826), mask ports (US Patent 6,439,230), and cushion clips (US Patent 6,412,487). The contents of all these patents are hereby incorporated by cross-reference.

[0009] Another known mask assembly the PAPILLION™ mask, manufactured by MAP, Germany is shown in Austrian Design Registrations #50770 and #50771 (and US Design Patent D484,237 and Australian Design Registration Application 2153/2002).

[0010] Since mask systems for treating sleep disordered breathing have to be worn for several hours every night while a patient sleeps, designers strive to make them comfortable. In particular, they strive to attempt to eliminate the mask system being a source of pressure sores on a patient's face.

[0011] A problem which can occur in prior art mask systems is that there can be drag forces from the tube which when transferred through the elbow can disrupt the seal of the cushion on the face.

[0012] One solution to this problem is found in US 6,039,044. It is an aspect of the invention to provide at least an alternative solution to this problem.

[0013] A difficulty with some prior art mask assemblies is that those which achieve a clinically effective seal while being comfortable to wear each night at home can be expensive to manufacture. Headgear can represent a significant proportion of the cost of manufacturing a mask system. The manufacturing costs are passed onto customers which leads to a more expensive mask assembly for patients. This may in turn mean that fewer patients

can afford treatment. This may also mean that there can be a tendency for clinics and hospitals to reuse masks among numerous patients. Unless thorough hygiene systems are put in place to manage cross-infection it is not advised that a mask be re-used by different patients. In general, particularly in hospitals with the advent of respiratory diseases such as SARS, it is desirable to have a mask system which is cheap enough to be disposable.

[0014] It is a further aspect of the invention to provide a low cost mask assembly for treating sleep disordered breathing.

[0015] It is a further aspect of the invention to provide a disposable mask assembly for treating sleep disordered breathing.

## SUMMARY OF THE INVENTION

[0016] Throughout this specification and claims, a combination shell and cushion will hereinafter be referred to as a "shell/cushion". Whilst this is done for convenience, where ever the expression "shell/cushion" appears it should be read as meaning the combined shell and cushion.

[0017] In accordance with a first aspect of the invention, there is provided a comfortable low cost mask system comprising headgear, a combination shell/cushion, a frame, elbow and retaining ring.

[0018] In accordance with another aspect of the invention, there is provided a low cost headgear.

[0019] In accordance with another aspect of the invention, there is provided a comfortable shell/cushion which has a reduced tendency to cause pressure points on a patient's face.

[0020] In one embodiment, a mask system for treating sleep disordered breathing comprises headgear, a shell/cushion including a channel adjacent a front aperture, a frame, an elbow including at least one undercut on a proximal end and a retaining ring including a rear flange adapted to be retainably insertable in the channel of the shell/cushion and a front flange adapted to retainably engage with the at least one undercut of the elbow.

[0021] There can be a thin walled section adjacent the channel of the shell/cushion which is adapted to tear upon removal of the elbow.

[0022] The elbow construction can help prevent separation of the aperture from the retaining ring during normal use.

[0023] The elbow when separate from the mask can have a cylindrical outlet.

[0024] The shell/cushion can include an annular flange which when assembled with the elbow or said connection piece engages a rim of said outlet to thereby suitably seal the outlet to said flange.

[0025] In another embodiment, a mask system for treating sleep disordered breathing comprises headgear, a frame, and shell/cushion including a frame-receiving channel defined by a front flange and a rear flange, the front flange extending 75% to 100% of the way around the perimeter of the shell/cushion, wherein the frame is adapted to be removably insertable in the frame-receiving channel of the shell/cushion.

[0026] This mask system can include at least a nasal bridge region of the shell/cushion adapted to contact the nasal bridge region of a patient. The rear flange of the nasal bridge region can be from 1mm to 3mm thick. The rear flange can be approximately 2mm thick.

[0027] In still another embodiment, a connection piece for connecting a mask to a conduit which can carry an air flow to said mask is provided. The connection piece includes an inlet and an outlet and a passage wall to carry the air flow therebetween, the connection piece including, in the vicinity of said outlet between said outlet and said

inlet, a vent wall extending away from the passage wall, the vent wall including at least one aperture therethrough.

[0028] The connection piece can be formed integrally with the mask. Alternatively the connection piece can be formed separately of the mask and can be joined or attached thereto.

[0029] The piece can be formed integrally with the conduit. Alternatively the connection piece can be formed separate from the conduit and can be joined or attached thereto.

[0030] The connection piece can be formed so that the outlet lies at any appropriate angle to the inlet. Preferably said outlet lies at an angle to the inlet which angle is in the range of 90° to 180°. The connection piece can be a 90° elbow.

[0031] The connection piece can include attachment structure to attach the connection piece to the mask. The attachment structure can include at least one snap-in undercut to engage a mating.

[0032] The attachment structure can releasably attach the connection piece to the mask.

[0033] The attachment structure can include moveable portions on which said snap-in undercuts are formed, the moveable portions allowing said undercuts to disengage the flange.

[0034] The attachment structure can allow rotation of said connection piece relative to said mask.

[0035] The connection piece can include a Luer port through the passage wall, which can be on a side and/or the front of said connection piece.

[0036] The vent wall can lay at an oblique angle to the air flow. The angle is preferably in the range of 25° to 155°.

[0037] The connection piece can include on its external surface a recess having wall portions extending away from an external side of said vent wall. The wall portions can diverge in a direction away from said vent wall.

[0038] In yet another embodiment, a mask for treating sleep disordered breathing includes a shell/cushion with an inner and outer surface, a flange extending away from the outer surface and surrounding the shell/cushion, the mask having an exoskeletal frame having a shape which substantially matches the contours of the flange so that it can be positioned adjacent the flange when the shell/cushion is in a shape suitable for use by a patient, and structure to hold said flange to the frame.

[0039] The structure to hold the flange to the frame can include one or more apertures through the flange.

[0040] Rivets or other fixers can pass through said apertures to hold the flange adjacent the frame.

[0041] The frame can be attached to headgear to position the mask onto a patient's head.

[0042] The frame can include connection members connected to the frame for cooperating therewith to sandwich the flange between said connection members and the frame. The connection members can be hinged to the frame, or connected to the frame by a flexible member.

[0043] A second frame of a shape which substantially matches the contours of the flange can be present, whereby said flange is sandwiched between the first frame and the second frame.

[0044] The second frame, the flange and the first ring member can be held together by rivets and/or fixers, etc.

[0045] The second frame can include rivets extending therefrom, which can pass through the flange and the first frame. Alternatively the first frame can include rivets extending therefrom, which can pass through the flange and the second frame. Another alternative is for the flange to include a first set of rivets extending in a forward

direction and a second set of rivets extending in a rearward direction, the first set of rivets being received in apertures through the first frame, the second set of rivets being received in apertures through the second frame.

[0046] The rivets can be deformable at their free end, or the aperture into which they protrude can be deformable.

[0047] The rivets can include an undercut so that the undercut can pass through the apertures to hold components together.

[0048] Another embodiment of the invention provides a mask system including head gear and mask as described above. This mask system can include a connection piece as described above.

[0049] These another aspects will be described in or apparent from the following detailed description of preferred embodiments.

## **BRIEF DESCRIPTION OF FIGURES**

[0050] Embodiments of the present invention will now be described by way of example only, with reference to the accompanying Figures, in which:

[0051] Figure 1 shows a perspective view of a mask system according to an embodiment of the present invention;

[0052] Figure 2 shows a front perspective view of a mask assembly similar to that used in the system of Figure 1, but having a different shell/cushion;

[0053] Figure 2A shows a front view of the mask assembly of Figure 2;

[0054] Figure 3 shows a side view of the mask assembly of Figure 2;

[0055] Figure 4 shows a rear view of the mask assembly of Figure 2;

[0056] Figure 5 shows a bottom view of the mask assembly of Figure 2;

[0057] Figure 6 shows a top view of the mask assembly of Figure 2;

[0058] Figure 7 shows an exploded view of the mask assembly of Figure 2;

[0059] Figure 8 shows a cross-section of the mask assembly of Figure 2;

[0060] Figure 9 shows a further cross-section of the mask assembly of Figure 2 superimposed over a side view;

[0061] Figure 10 shows a front perspective view of another mask assembly having the same shell/cushion used in figure 2, with a different frame;

[0062] Figure 11 shows an exploded view of another mask assembly near the face of a patient having a frame similar to that used in Figure 10 but with a shell/cushion similar to that used in Figure 1 and 7;

[0063] Figure 12 shows a side view of the mask assembly of Figure 11 including disposable headgear in use;

[0064] Figure 13 illustrates a front elevation of a three point frame as used in the mask assembly of Figure 2;

[0065] Figure 14 illustrates a cross section through lines XIV-XIV the frame of Figure 13;

[0066] Figure 15 illustrates a right side elevation of the frame of Figure 13;

[0067] Figure 16 illustrates a plan view of the frame of Figure 13;

[0068] Figure 17 illustrates an underneath view of the frame of Figure 13;

[0069] Figure 18 illustrates a cross section showing detail Z of Figure 14;

[0070] Figure 19 illustrates a left hand side perspective view of the frame of Figure 13;

[0071] Figure 20 illustrates a right hand side perspective view of the frame of Figure 13;

- [0072] Figure 21 illustrates a front elevation of a five point frame as used in the mask assembly of Figures 10 and 11;
- [0073] Figure 22 illustrates a cross section through lines XXIII-XXIII the frame of Figure 21;
- [0074] Figure 23 illustrates a left side elevation of the frame of Figure 21;
- [0075] Figure 24 illustrates an underneath view of the frame of Figure 21;
- [0076] Figure 25 illustrates a plan view of the frame of Figure 21;
- [0077] Figure 26 illustrates a front elevation of a retaining ring;
- [0078] Figure 27 illustrates a cross section through the lines XXVII-XXVII of the retaining ring of Figure 26;
- [0079] Figure 28 illustrates a side elevation of the retaining ring of Figure 26;
- [0080] Figure 29 illustrates a perspective view of the retaining ring of Figure 26;
- [0081] Figure 30 illustrates a front elevation of a connection piece or elbow;
- [0082] Figure 31 illustrates a right side view of the elbow of Figure 30;
- [0083] Figure 32 illustrates a cross section through the line XXXII-XXXII of the elbow of Figure 30;
- [0084] Figure 33 illustrates a cross section through the line XXXIII-XXXIII of the elbow of Figure 30;
- [0085] Figure 34 illustrates a plan view of the elbow of Figure 30;
- [0086] Figure 35A illustrates a lower rear perspective view of the elbow of Figure 30;
- [0087] Figure 35B illustrates an upper front perspective view of the elbow of Figure 30;
- [0088] Figure 36 illustrates detail X of the cross section of Figure 33;
- [0089] Figure 37 illustrates detail Z of the cross section of Figure 32;
- [0090] Figure 38 illustrates a front elevation of a connection piece or elbow for single use;
- [0091] Figure 39 illustrates a left side view of the elbow of Figure 38;
- [0092] Figure 40 illustrates a cross section through the line XL-XL of the elbow of Figure 38;
- [0093] Figure 41 illustrates a plan view of the elbow of Figure 38;
- [0094] Figure 42 illustrates a cross section through the line XLII-XLII of the elbow of Figure 38;
- [0095] Figure 43 illustrates a lower rear perspective view of the elbow of Figure 38;
- [0096] Figure 44 illustrates an upper front perspective view of the elbow of Figure 38;
- [0097] Figure 45 illustrates detail Z of the cross section of Figure 40;
- [0098] Figure 46 illustrates detail X of the cross section of Figure 42;
- [0099] Figure 47 illustrates a front elevation of a shell/cushion having four points or channels spaced around the periphery to attach a frame;
- [00100] Figure 48 illustrates a right side elevation of the shell/cushion of Figure 47;
- [00101] Figure 49 illustrates a cross section through the line XLIX-XLIX of the shell/cushion of Figure 47;
- [00102] Figure 50 illustrates a plan view of the shell/cushion of Figure 47;
- [00103] Figure 51 illustrates a cross section through the line LI-LI of the shell/cushion of Figure 47;
- [00104] Figure 52 illustrates detail Z of the cross section of Figure 49;
- [00105] Figure 53 illustrates a cross section through line LIII-LIII of the shell/cushion of Figure 48;
- [00106] Figure 54 illustrates a lower rear perspective view of the shell/cushion of Figure 47;
- [00107] Figure 55 illustrates an upper front perspective view of the shell/cushion of Figure 47;

- [00108] Figure 56 illustrates a front elevation of a shell/cushion having a continuous channel around the periphery to attach a frame;
- [00109] Figure 57 illustrates a right side elevation of the shell/cushion of Figure 56;
- [00110] Figure 58 illustrates a cross section through the line LVIII-LVIII of the shell/cushion of Figure 56;
- [00111] Figure 59 illustrates a plan view of the shell/cushion of Figure 56;
- [00112] Figure 60 illustrates an underneath view of the shell/cushion of Figure 56;
- [00113] Figure 61 illustrates a cross section through line LXI-LXI of the shell/cushion of Figure 57;
- [00114] Figure 62 illustrates the side elevation of a mask assembly of the shell/cushion of Figures 56 to 61, the frame of Figures 13 to 20 and the elbow of Figures 30 to 37;
- [00115] Figure 63 illustrates a cross section through the line LXIII-LXIII of the mask assembly of Figure 62;
- [00116] Figure 64 illustrates a cross section through the line LXIV-LXIV of the mask assembly of Figure 62;
- [00117] Figure 65 illustrates a cross section through the line LXV-LXV of the mask assembly of Figure 62;
- [00118] Figure 66 illustrates a cross section through the line LXVI-LXVI of the mask assembly of Figure 62;
- [00119] Figure 67 shows headgear in accordance with a disposable embodiment of the invention;
- [00120] Figure 68A shows a shell/cushion with a bellows portion demonstrating decoupling of the torque transfer between the elbow and the cushion;
- [00121] Figure 68B shows the shell/cushion of Figure 68A whereby the bellows portion is in the action of decoupling torque;
- [00122] Figure 69 illustrates a front elevation of a frame;
- [00123] Figure 70 illustrates a right side elevation of the frame of Figure 69;
- [00124] Figure 71 illustrates a cross section through the line LXXI-LXXI of the frame of Figure 69;
- [00125] Figure 72 illustrates a cross section through the line LXXII-LXXII of the frame of Figure 69;
- [00126] Figure 73 illustrates a cross section through the line LXXIII-LXXIII of the frame of Figure 69;
- [00127] Figure 74 illustrates a rear elevation of the frame of Figure 69;
- [00128] Figure 75 illustrates in detail a portion from the cross section of Figure 71;
- [00129] Figure 76 illustrates in detail a portion from the cross section of Figure 72;
- [00130] Figure 77 illustrates a right side perspective view of the frame of Figure 69;
- [00131] Figure 78 illustrates a left side perspective view of the frame of Figure 69;
- [00132] Figure 79 illustrates a front elevation of a clip for use with the frame of Figure 69;
- [00133] Figure 80 illustrates a right side elevation of the frame of Figure 79;
- [00134] Figure 81 illustrates a cross section through the line LXXXI-LXXXI of the frame of Figure 79;
- [00135] Figure 82 illustrates a cross section through the line LXXXII-LXXXII of the frame of Figure 79;
- [00136] Figure 83 illustrates a cross section through the line LXXXIII-LXXXIII of the frame of Figure 79;
- [00137] Figure 84 illustrates a rear elevation of the frame of Figure 79;
- [00138] Figure 85 illustrates in detail a portion from the cross section of Figure 82;
- [00139] Figure 86 illustrates in detail a portion from the cross section of Figure 83;
- [00140] Figure 87 illustrates a right side perspective view of the frame of Figure 79;
- [00141] Figure 88 illustrates a left side perspective view of the frame of Figure 79;



- [00142] Figure 89 illustrates a front view of an elbow according to yet another embodiment of the present invention;
- [00143] Figure 90 illustrates a cross section through the line XC-XC of the elbow of Figure 89;
- [00144] Figure 91 illustrates a cross section through the line XCI-XCI of the elbow of Figure 89;
- [00145] Figure 92 illustrates a plan view of the elbow of Figure 89;
- [00146] Figure 93 illustrates a cross section through the line XCIII-XCIII of the elbow of Figure 89;
- [00147] Figure 94 illustrates in detail a portion of the cross section of Figure 93;
- [00148] Figure 95 illustrates in detail a portion of the cross section of Figure 90;
- [00149] Figure 96 illustrates in detail a portion of the cross section of Figure 91;
- [00150] Figure 97 illustrates a lower rear perspective of the elbow of Figure 89;
- [00151] Figure 98 illustrates an upper front perspective of the elbow of Figure 89;
- [00152] Figure 99 illustrates a front view of a further elbow;
- [00153] Figure 100 illustrates a cross section through the line C-C of the elbow of Figure 99;
- [00154] Figure 101 illustrates a cross section through the line CI-CI of the elbow of Figure 99;
- [00155] Figure 102 illustrates a cross section through the line CII-CII of the elbow of Figure 99;
- [00156] Figure 103 illustrates a cross section through the line CIII-CIII of the elbow of Figure 99;
- [00157] Figure 104 illustrates in detail a portion of the cross section of Figure 103;
- [00158] Figure 105 illustrates in detail a portion of the cross section of Figure 100;
- [00159] Figure 106 illustrates in detail a portion of the cross section of Figure 101;
- [00160] Figure 107 illustrates a lower rear perspective of the elbow of Figure 99;
- [00161] Figure 108 illustrates an upper front perspective of the elbow of Figure 99;
- [00162] Figure 109 illustrates a front view of another shell/cushion;
- [00163] Figure 110 illustrates a cross section through the line CX-CX of the shell/cushion of Figure 109;
- [00164] Figure 111 illustrates a cross section through the line CXI-CXI of the shell/cushion of Figure 109;
- [00165] Figure 112 illustrates a right side elevation of the shell/cushion of Figure 109;
- [00166] Figure 113 illustrates a plan view of the shell/cushion of Figure 109;
- [00167] Figure 114 illustrates in detail a portion of the cross section of Figure 111;
- [00168] Figure 114A illustrates in detail a portion of the shell/cushion in the nasal bridge region;
- [00169] Figure 115 illustrates in detail a portion of the cross section of Figure 110;
- [00170] Figure 116 illustrates an upper front perspective of the shell/cushion of Figure 109;
- [00171] Figure 117 illustrates a lower rear perspective of the shell/cushion of Figure 109;
- [00172] Figure 118 illustrates a front elevation of another retaining ring for use with the shell/cushion of Figure 109;
- [00173] Figure 119 illustrates a side view of the ring of Figure 118;
- [00174] Figure 120 illustrates a diametrical cross section through the ring of Figure 118;
- [00175] Figure 121 illustrates a perspective view of the ring of Figure 118;
- [00176] Figure 122 illustrates an exploded perspective view of the a mask assembly comprising the components of the frame of Figure 69, the clip of Figure 79, the elbow of Figure 99 and the shell/cushion of Figure 109;

- [00177] Figure 123 illustrates the mask assembly of Figure 122, with all components shown in assembled condition, with some components being shown in cross section;
- [00178] Figure 124 illustrates a detailed cross section through a rivet, shell/cushion aperture and front frame aperture of Figure 122, which are located at the bottom of the mask assembly;
- [00179] Figure 125 illustrates a cross section through the retaining ring of the mask assembly of Figures 122 and 123, with the left half showing one arrangement and the right half showing another arrangement to seal the shell/cushion and the elbow; and
- [00180] Figure 126 illustrates a side view of a such as that illustrated in figures 69 to 78, wherein two rivet systems are formed integrally therewith.

## **DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

### **§ 1 Introduction**

- [00181] In various forms the embodiments provides a comfortable low cost mask system which has few components and for example, has a single walled cushion. In a preferred form it does not include a forehead support, nor headgear clips, but it will be readily understood that these can be included if desired.
- [00182] The embodiments include a mask system which provides a patient interface having a range of interchangeable sub-components as part of a device for delivering a supply of air at positive pressure to the airways of a patient in the treatment of sleep disordered breathing. The mask system includes headgear and a mask assembly(see Figure 1).
- [00183] Multiple versions of the mask system are described with respect to the drawings:
- [00184] Version 1: as depicted in Figures 1 and 7 being reusable with components which disassemble for cleaning with a three point single piece frame and having a shell/cushion with a continuous channel to receive the frame;
- [00185] Version 2: as depicted in Figures 2 to 6, 8 and 9, being reusable with components which disassemble for cleaning with a three point single piece frame and having a shell/cushion with four discrete channels to receive the frame;
- [00186] Version 3: depicted in Figure 10 being a single use or disposable unit with components which disassemble for cleaning with a five point single piece frame;
- [00187] Version 4; depicted in Figure 11 being a reusable unit with components which disassemble for cleaning with a five point single piece frame;
- [00188] Version 5: is not illustrated per se, but is a single use or disposable unit with a three point two piece frame;
- [00189] Version 6: is not illustrated per se, but is a reusable unit with components which disassemble for cleaning with a three point two piece frame;
- [00190] Version 7: is a single or disposable unit, such as in versions 3 or 5 with an elbow or connection piece as depicted in Figures 99 to 108;
- [00191] Version 8: is a reusable unit, such as in versions 1, 3, 5 with an elbow or connection piece as depicted in Figures 89 to 98; and

[00192] Version 9: is not illustrated per se, but is a reusable or single use unit of any of the previous eight versions, with a shell/cushion as depicted in Figure 68.

[00193] The embodiments also include four versions of elbows or connection pieces for connecting a mask to a conduit, whereby the connection piece completes the mask:

[00194] Version A: is a reusable disconnectable elbow as depicted in Figures 30 to 37;

[00195] Version B: is a single use elbow which once assembled to a mask cannot be disassembled therefrom and is as depicted in Figures 38 to 46;

[00196] Version C: is a reusable disconnectable elbow as depicted in Figures 89 to 98; and

[00197] Version D: is a single use elbow which once assembled to a mask cannot be disassembled therefrom and is as depicted in Figures 99 to 108.

[00198] The embodiments further include five versions of frames, which connect to the shell/cushions and the headgear to position the mask assemblies on a patient:

[00199] Version (i): a single piece three point frame receiveable in a channel in a shell/cushion as depicted in Figures 13 to 20;

[00200] Version (ii): a single piece five point frame receiveable in a channel in a shell/cushion as depicted in Figures 21 to 25;

[00201] Version (iii): a two piece three point frame as depicted in Figures 69 to 88, which will sandwich a flange on a shell/cushion to provide the shell/cushion with an exoskeletal support structure.

[00202] Version (iv): which is not illustrated, but us a two piece five point frame, which will sandwich a flange on a shell/cushion to provide the shell/cushion with an exoskeletal support structure. This version will be similar to Version (iii) as depicted in Figures 69 to 88; and

[00203] Version (v): which is not illustrated, where the frame is a single piece and rivets to a flange on the shell/cushion.

[00204] The embodiments further include eight versions of shell/cushions:

[00205] Version I: being as depicted in Figures 1, 7, and 56 to 66, whereby the shell/cushion has a single continuous channel to receive the frame, for re-use duty;

[00206] Version II: being as depicted in Figures 1, 7, and 56 to 66, whereby the shell/cushion has a single continuous channel to receive the frame, for single use duty;

[00207] Version III: being as depicted in Figures 2 to 6, and 47 to 55, whereby the shell/cushion has a plurality of discrete channels to receive the frame, for re-use duty;

[00208] Version IV: being as depicted in Figures 2 to 6, and 47 to 55, whereby the shell/cushion has a plurality of discrete channels to receive the frame, for single use duty;

[00209] Version V: being as depicted in Figures 109 to 117, whereby a flange is provided around the periphery and is for re-use duty;

[00210] Version VI: being as depicted in Figures 109 to 117, , whereby a flange is provided around the periphery and is for single use duty;

[00211] Version VII: is not illustrated but is similar to the shell/cushion of Figures 109 to 117, except that it has a plurality of discrete flanges or housing around the apertures and is for re-use duty; and

[00212] Version VIII: is not illustrated but is similar to the shell/cushion of Figures 109 to 117, except that it has a plurality of discrete flanges or housing around the apertures and is for single use duty.

[00213] As illustrated in Figure 1, the mask system 1, generally comprises a mask assembly 10 having a shell/cushion 30, a frame 40, a connecting piece or elbow 50 and a retaining ring 60 (which is not visible in figure 1, but is visible in figure 7). As will be readily understood, the combination of the versions of the basic components as described above will yield a multitude of mask system configurations.

## **§ 2 Headgear**

[00214] The headgear 20, as illustrated in Figures 1, 12 and 67 is composed of three separate strap pieces 20.1, 20.2 and 20.3 which are comprised of white non-latex elastic tape joined together to form a three point headgear system. Headgear 20 is attached to the frame 40 via the button holes 20.4 in the straps 20.1 and 20.2.

[00215] Table 1 shows exemplary dimensions of each of the straps 20.1, 20.2 and 20.3.

<i>Drawing ref</i>	<i>Strap length (mm)</i>	<i>Quantity</i>
20.1	500-700	1
20.2	350-500	1
20.3	150-250	1

Table 1

[00216] Button holes (3-5mm) are placed in the middle along the entire length of the straps with gaps between two button holes of approximately 3.5-6.5mm. The straps 20.1, 20.2 and 20.3 are each 20mm wide and constructed from a knitted 70% polyester and 30% non-latex elastomer which is white and biocompatible. The elasticity of the preferred material is 49 +/- 20 Newtons per metre Nm<sup>-1</sup>. The above dimensions and materials are exemplary only.

[00217] Ordinarily headgear can represent a significant cost in the manufacture of a mask system. Thus, by manufacturing the headgear 20 from this particular low cost material can lead to a significant cost saving for the headgear and the mask system as a whole.

[00218] The headgear 20 described above is preferably used for a single use and then disposed of. However, to make the headgear in a reusable form, the headgear can be moulded in a number of parts and joined together with buttons or similar. Alternatively reusable headgear can be moulded in one piece.

[00219] Figure 67 shows a plan view of the headgear 20 while Figure 12 shows the headgear 20 in use on a model head.

## **§ 3 Shell/Cushion**

[00220] Illustrated in Figures 1, 7, 11, and 56 to 66 is the shell/cushion 30. The shell/cushion 30 defines a nose-receiving cavity 30.1 and forms a seal with the face of the patient. The shell/cushion 30 has a rearward aperture 30.2 through which the patient's nose passes in use and a front aperture 30.3 to which a connection piece or elbow 50 is attached. In a preferred form, the shell/cushion 30 is single walled, however in other forms it may have two or more walls, similar to the mask as taught in US Patent 6,112,746 (incorporated herein by reference), known by the trade mark MIRAGE®. The shell/cushion 30 has a sealing structure 30.5 and a support structure 30.4 of a

substantially constant cross section. It can be moulded from any appropriate material such as silicone or a thermoplastic elastomer.

[00221] The sealing structure 30.5 has a face contacting side 30.51 adapted to form a seal on a patient's face. The face contacting side 30.51 includes a nasal bridge region 30.6, side regions 30.7 and a lip region 30.8. As can be seen from the figures the lip region 30.8 has a series of four vent orifices 30.9 passing therethrough. The face contacting side 30.51 is similar in shape to the face contacting side of the mask known by the trade mark PAPILLION (manufactured by MAP GmbH) or the mask known by the trade mark MIRAGE (manufactured by ResMed Limited).

[00222] A range of shell/cushion 30 sizes can be provided to suit different sizes of noses. For example, in one form, shell/cushions can have a shallow nasal bridge region 30.6.

[00223] The shell/cushion 30 includes a frame-receiving channel 140 defined by a front flange 34 and a rear flange 36. The shell/cushion 30 of Figure 7, 8 and 56 to 61 has the front flange 34 of a frame-receiving channel 140 as a continuous or unbroken channel, which extends 100% of the way around the perimeter of the shell/cushion 30.

[00224] As is visible in Figure 56, the rear flange 36 is somewhat wider in the lip region 30.8 and side regions 30.7. In these wider portions on both the side regions 30.7 are elongated recesses 30.75 which provide an additional structure to engage and locate the frame 40 or 140, as will be described below.

[00225] Illustrated in Figures 2 to 6, 8, 9, 10 and 47 to 55 is another a shell/cushion 130. The shell/cushion 130 is similar to the shell/cushion 30 and like parts have been like numbered. The shell/cushion 130 differs from the shell/cushion 30 in that instead of a continuous or unbroken channel 140 being provided all the way around the shell/cushion, discrete channels 140.1, 140.2 and 140.3 are provided to cooperate with a fourth channel 140.4 (see Figure 48) to form four discrete points to receive four points on a frame 40 therein. Each channel discrete 140.1, 140.2, 140.3 and 140.4 is formed between a continuous rear flange 36, and an intermittent front flange 34. The rear flange 36 surrounds the shell/cushion 130 all the way around the periphery thereof, so as to provide a flange against which the frame 40 or 140 can push. The portion of the rear flange 36 in the lower side regions 30.7 and lip region 30.8 are thicker than in the nasal bridge region 30.6 so as to prevent a "knife edge" forming in the nasal bridge region 30.6, but provide structure to form the two lower apexes of the shell/cushion 30.

[00226] The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in Figure 3. The wall section 30.10 has two functions. The first is to form a front flange which with the rear flange 36 in the lip region 30.8 forms the lower channel 140.4. The second function is that the wall section 30.10 allows the vent orifices 30.9 to be positioned at an angle with respect to the elbow. However, the vent orifices 30.9 can be constructed at a flatter angle, for example, 10° to 15° from the vertical (with respect to the orientation shown in Figure 3) so that when a patient is wearing the mask system 1 and lying down, the vent orifices 30.9 will be aligned generally at 10° to 15° from the horizontal).

[00227] As illustrated in Figure 4, 8, 9, 48, 49, 56 and 57 the rear flange 36 of the frame-receiving channel 140 has different thickness in different regions. This feature is common to both shell/cushions 30 and 130, but for convenience is described in the proceeding passages with respect to shell/cushion 30 only. It is thinner in the nasal bridge region 30.6 than in the lower side regions 30.7 and the lip region 30.8. The rear flange 36 is between 1 to

3mm thick, preferably 2mm thick in the nasal bridge region 30.6, but can be of the order of 5mm in the lower side regions 30.7 and lip region 30.8. This provides sufficient support for the sealing structure 30.5 of the shell/cushion 30 in the nasal bridge region 30.6 but doesn't lead to the creation of a "knife-edge" which can be uncomfortable for a patient. A "knife edge" may form if the sealing structure 30.5 of the shell/cushion 30 collapses, and if a harder or thicker portion of the shell/cushion 30 was used at the nasal bridge region 30.6. A "knife edge" is undesirable because with prolonged use, it can create a pressure sore on a patient's face. Figures 63 and 64 show sections from Figure 62 with thicker rear flange regions 36, whereas similar rear flange sections 36 in Figure 65 and 66 are shown with thinner rear flange regions.

[00228] Thus, as can be seen from the shell/cushion 30 and 130, the shell/cushion can be provided with discrete channels or a continuous channel. The channel or channels can, when their length is totalled, be in the range of 75% to 100% of the perimeter of the shell/cushion as in the case of shell/cushion 30 or in the range of 20% to 40% as in the case of shell/cushion 130 of the frame 40. An advantage of the front flange extending 75% to 100% of the way around the perimeter is that it is less likely to be removed by inadvertence. From Figure 56 and 47 it can be seen that the shell/cushions 30 and 130 have the wider portion of the rear flange 36 extending around the two lower apexes, so as to occupy approximately 60% of periphery of the shell/cushion 30 and 130. To achieve the desired structural function and flexibility in the nasal bridge region, this wider flange could occupy approximately 40% to 80% of the periphery of the shell/cushions 30 and 130 centered around the lower regions thereof.

[00229] Figure 52 shows in cross-section a portion 30.31 of the shell/cushion 130. The portions 30.31 are those portions linked to the front aperture 30.3, which will receive the retaining ring 60. The region 30.31 has a channel 524 into which the rear flange of the retaining ring 60 will be received. The patient end of the aperture has an annular flap 526 which is relatively thin and flexible, and which reduces the inside diameter of the aperture 30.3. The purpose of the flap 526 is to provide a seal with a portion of the connection piece or elbow 50, as will be described below in chapter §7 Assembly of the components below.

[00230] The section 522 as illustrated in Figure 52 is a relatively thin walled section. Such a thin walled section is particularly useful for the manufacture of a disposable mask. The thin walled section 522 can thus be designed to tear if a person attempts to remove the connection piece or elbow 50, for example to wash the elbow 50. This aspect represents a safety feature preventing re-use of a disposable mask having a shell/cushion 130, reducing the likelihood of cross-infection.

[00231] Alternatively, if the shell/cushion 130 were to be reusable then the section 522 will be provided with a thicker dimension which would prevent the section 522 tearing at the time of disassembly. The shell/cushion 30, being of a reusable nature, will have a cross section similar to that of Figure 52 with the section 522 being of a thicker dimension than that for shell/cushion 130.

[00232] Illustrated in Figure 68 is a diagrammatic representation of a modified shell/cushion 230. In this shell/cushion 230 a small bellows portion 230.1 is provided (or alternatively a flexible neck can be provided) adjacent the aperture 30.3 where a connection piece or elbow 50 fits into the shell/cushion 230. This bellows portion 230.1 provides a flexible element which allows movement between the connection piece or elbow 50 and the shell/cushion 230. By providing this flexibility there is a decoupling of any torque which may attempt to transfer between the elbow and the shell/cushion.

[00233] Illustrated in Figures 109 to 117, 122 and 123 is another shell/cushion 330, which is similar to the shell/cushions 30 and 130 described above with like parts being like numbered. The shell/cushion 330 differs from the shell/cushions 30 and 130 in that instead of a channel 140, or a series of discrete channels 140.1, 140.2, 140.3 and 140.4 being provided around the periphery to receive a frame 40, a continuous peripheral flap or flange 330.1. The flange 330.1 has the same shape as a two piece frame (see description below with respect to Figures 69 to 88) which will sandwich the flange 330.1.

[00234] The flange 330.1 includes seven apertures 330.2 and 330.3 therethrough. The four apertures 330.2 are of an approximate diameter of 5.75mm while the three apertures 330.3 are of an approximate diameter of 3mm. The apertures 330.2 and 330.3 receive therethrough rivets formed on one piece of the two piece frame as will be described below. As the rivets which pass through the apertures 330.2 have a barbed head which is of a larger diameter than the shank the apertures 330.2 are of a larger diameter to accommodate this large diameter barb.

[00235] While Figures 109 to 117 display a continuous flange 330.1 around the periphery of the shell/cushion 330, a satisfactory result is also expected should a series of seven discrete flanges or housing were to be provided around the apertures 330.2 and 330.3. Whilst this will give the frame which sandwiches these flanges some seven points of grip or contact with shell/cushion, these seven points are expected to be sufficient to maintain the shape of the shell/cushion when it is in use.

[00236] As can be seen from Figure 114 the exterior of the shell/cushion 330, which provides a seal with a patients face, has a shot blasted surface finish. Such a shot blasted finish will provide a more comfortable feel for the patient. The cross section of figure 114 is taken through the middle region of the shell/cushion 330. It can be seen in figure 114, that in the region designated by the wall 330.11, behind the flange 330.1, the thickness of the wall 330.11 is kept relatively thick and then tapers in a rearward direction. In contrast to this, as is illustrated in figure 114A, in the nasal bridge region 30.6, the cross section is different, whereby the wall 330.11 (shown for comparison in phantom line) is thinned to form the wall 330.12 which is a relatively thinner and substantially constant cross section wall portion. This reduction in wall thickness in the nasal bridge region 30.6 helps to reduce the chances of a "knife edge" being formed in use on a patient, in the nasal bridge region 30.6.

[00237] Illustrated in figures 109, 110, 112, and 113 the shell/cushion 330 is illustrated as having a manufacturing tab or de-moulding tab 330.13. The de-moulding tab 330.13 allows a robotic de-moulder to grab the shell/cushion 330 safely and securely, without having to grab any other parts of the shell/cushion 330. This can limit the possibility of damaging any of the other parts of the shell/cushion 330 in the process of cutting off any excess material by a robot which may have resulted from the moulding process.

[00238] The shell/cushion 330 is specifically for one time hospital use. As can be seen from Figure 115, the shell/cushion 330 has a thin walled section, approximately 0.33 to 0.75 mm in thickness. As described above this will provide a line of weakness allowing the shell/cushion to tear, should it be attempted to remove the retaining ring 60 from the recess 524. The propensity to tear limits the ability to clean the shell/cushion 330 before re-use, thus preventing re-use.

[00239] To provide some additional rigidity whilst at the same time keeping the material used to a optimum level, there is provided on the shell/cushion 330 a series of four radially extending reinforcing ribs 330.4 which extend away from a generally circular reinforcing ring 330.6 which surrounds the region 30.31 and aperture 30.3. The ribs 330.4 and 330.6 are formed integrally in the shell/cushion 330, but are of a greater thickness of material

than the regions 330.5. The ribs 330.4 and 330.6 are approximately 2 to 3mm in thickness while the regions 330.5 are approximately 1 to 1.5 mm in thickness. This arrangement helps to provide better aesthetic quality while also providing greater structural support where required, but a softer feel at the seal locations.

#### **§ 4 Frame**

[00240] As is illustrated in Figures 1 to 9, and 12 to 18, the frame 40 is shaped and adapted to be mounted on the shell/cushion 30 and 130, and provides anchor points 132 having apertures 40.1, 40.2 and 40.3 for headgear 20. The frame 40 provides three anchor points 132 and is shown in detail in Figures 13 to 20.

[00241] The frame 40 is of a generally triangular shape with rounded apexes, and has a base approximately 90mm wide and a height of approximately 84mm. Other exemplary dimensions are as indicated in the Figures 13 to 20.

[00242] The frame 40 can be made to any suitable configuration of anchor points 132 so as to provide a variety of fittings to suit the particular needs of individual uses. In this regard, the placement of anchor points 132 can be changed in a manner described in the published PCT patent application WO 02/45784, the contents of which are hereby incorporated by cross reference. In this way the adaptability of the mask system 1 is enhanced as the mask frame 40 is relatively inexpensive to manufacture.

[00243] Each anchor point 132 is formed from a frame member 132.2 which surrounds an aperture 40.1, 40.2 or 40.3. The apertures 40.1, 40.2 and 40.3 allows the ends of the straps 20.1 and 20.2 to be threaded therethrough.

[00244] On a middle portion of the frame member 132.2 is a mushroom headed spigot 132.1, which can be threaded though one of the button holes 20.4 on the respective ends of the straps 20.1 and 20.2. In alternative embodiments the spigot may be replaced by other methods of retention such as hooks.

[00245] If desired the user need not thread through the apertures 40.1, 40.2 or 40.3, and instead attach directly onto the mushroom headed spigots 132.1, however, there is less likelihood of inadvertent disconnection when in use if the ends of straps 20.1 and 20.2 are threaded through the respective apertures 40.1, 40.2 or 40.3 as all movement of the ends of the straps 20.1 and 20.2 will not tend to try to pull the button holes 20.4 over the mushroom headed spigots 132.1.

[00246] Figure 18 shows a detailed view of the mushroom headed spigot 132.1 of an anchor point 132 in cross-section from Figure 14. In use, a patient selects the appropriate button hole 20.4 of the headgear 20 and then passes it through the apertures 40.1, 40.2 or 40.3 and over a mushroom headed spigot 132.1 on the frame 40 to set the headgear straps at the appropriate length.

[00247] The frame 40 has rearwardly projecting ribs 40.7, in the vicinity of the two lower anchor point 132, near to the base of the frame 40. The ribs 40.7 are sized and shaped so as to be received into the elongated recesses 30.75 on the shell/cushions 30 and 130.

[00248] The frame 40 provides an indent 40.4 which also extends away from the face of the patient as is illustrated in Figures 14 and 15. This indent 40.4 helps to provide space for the nasal bridge section of the shell/cushion 30 or 130, without exerting a pressure point onto the patient's nasal bridge.

[00249] As is illustrated in Figures 10, 11 and 21 to 25 is another frame 140 which is similar to the frame 40 of Figures 14 and 15 and like parts have been like numbered. The difference between the frame 40 and the frame 140 is that the frame 140 provides up to five anchor points 132.



[00250] The upper anchor point 132 includes a three sided frame member 132.2, and on each side of the frame member 132.2 is located, at a generally central location a mushroom headed spigot 132.1.

[00251] The frame 140 can thus be used with the headgear 20 described above which provides three ends of straps 20.1 and 20.2, or it can be used with a modified form of headgear(not illustrated) with five straps.

[00252] As an alternative (not illustrated), the frame 140 may also provide four anchor points 132 and be used with a modified form of headgear (not illustrated) with four straps.

[00253] Preferably each of three straps that can be used with the upper anchor point 132 will be threaded through the aperture 40.2, whereby the straight sided nature of the three sides will interact with a respective mushroom headed spigot 132.1 to firmly secure the ends of the straps thereto.

[00254] Illustrated in Figures 69 to 78 is a first piece 240 of a frame for use with the shell/cushion 330 of Figures 109 to 117, and 122 and 123. The piece 240 is the outward facing portion of the frame once assembled.

[00255] Illustrated Figures 79 to 88 is a second piece 340 of the frame for use with the shell/cushion 330 of Figures 109 to 117, 122 and 123. The piece 340 is the inward facing portion of the frame once assembled.

[00256] The pieces 240 and 340 are of similar overall shape to the frames 40 and 140, and like parts are like numbered.

[00257] The piece 240 receives and secures the piece 340 therein, by means of four large diameter apertures 240.1, which as can be seen most clearly from Figures 72 and 76 have a tapered entry way 240.2 formed in a rearwardly extending cylindrical wall 240.21. In alternative embodiments, there may be between one and five large diameter apertures 240.1. The tapered entry way 240.1 leads to a constricted aperture 240.4 and a larger diameter recess 240.3 on the other side of constructed aperture to the entry way 240.2. The larger diameter recess 240.3 has at its base a shoulder 240.5.

[00258] The apertures 240.1 receive rivets 340.1 on the piece 340. As can be seen from Figures 82, 83, 85 and 86 and the rivets 340.1 have a tapered shank 340.2 and a tapered mushroom head 340.3, the underside of which has a shoulder 340.6. Surrounding the base of the shank 340.2 is a housing 340.4 which has an annular recess 340.5 between the base of the shank 340.2 and the housing 340.4. The tapered end of the mushroom head 340.3 allows the head 340.3 to push through the entry way 240.2 and the aperture 240.4, and once through, shoulders 340.6 and 240.3 will be adjacent each other preventing the withdrawal of the rivet 340.1 from the aperture 240.1.

[00259] The piece 240 includes three blind holes 240.6 into which will be received respective straight sided spigots 340.7. In alternative embodiments there may be differing numbers of blind holes and respective straight sided spigots, for example a number of blind holes and respective spigots between one and seven.

[00260] Illustrated in figure 126 is a frame 440 which is similar to the frame piece 240 of figures 69 to 78. Accordingly, like parts have been like numbered. The frame 440 differs from the frame 240 in that the frame 440 does not require a second frame member to be used therewith. Instead the frame 440 has a rivet 440.1 located adjacent each aperture 240.1. The rivets 440.1, of which only one is illustrated for convenience, has a lanyard 440.3 which ties the rivet 440.1 to the frame 440. A bearing surface 440.4 is provided from which extend the rivet shaft 440.5 which terminates in a mushroom head 440.6. The rivet 440.1, including the lanyard 440.3 can be integrally moulded with the frame 440, and provides an easy means of assembly.

[00261] To assemble the rivet 440.1, the frame 440 is placed adjacent the flange 330.1 of the shell/cushion 330, then the rivet 440.1 is moved into position against the rear face of the flange 330.1 and pushed home so that the bearing surface 440.4 can sandwich or compress the flange 330.1 to the rear face of the frame 440.

[00262] For the sake of illustration the aperture 240.1 near the bottom of the frame 440 has a different rivet structure associated with it. The rivet 440.2 has relatively thin panel 440.7 which extend away from the frame 440. A second panel 440.8 is hinged by a hinge 440.9 to the panel 440.7. Extending away from the panel 440.8 is a rivet shaft 440.5 which terminates in a mushroom head 440.6, in much the same way as the rivet 440.1.

[00263] The distance between the hinge 440.9 and the frame 440 (the height of the panel 440.7) can be sized to provide either a loose or snug fit around the flange 330.1, or if desired sized to provide as much compression of the flange 330.1 as possible. By positioning the flange 330.1 adjacent the aperture 240.1 and folding the panel 440.8 over so that the head 440.6 of the rivet is pushed home into the aperture 240.1, the rivet 440.2 will hold the flange 330.1 in place relative to the frame 440.

[00264] The frame 40, the pieces 240 and 340, and the frame 440 can be moulded from any appropriate material such as polycarbonate.

### **§ 5 Connection Piece or Elbow**

[00265] As is illustrated in Figures 1, 7, 9, 11, 12, 62 to 66, and most particularly in Figures 30 to 37, the elbow 50 has a distal end 52 which is adapted to engage, whether with or without a swivel or union 250.2 (see Figure 1) with an air delivery conduit (not shown). The union 250.2 is illustrated in Figure 1, but is optional. The manner by which the union 250.2 connects to the elbow 50, is that the internal cylindrical surface of the distal end 52 includes an annular groove 250.1 (see Figures 11, 32, 35A and 35B), which will receive an annular lip 250.3 on the swivel 250.2.

[00266] A proximal end 50.1 of the elbow 50 is adapted to engage with both a shell/cushion 30, 130, 230, 330 and a retaining ring 60 positioned within the aperture 30.3 of the shell/cushion. Two, circumferentially equispaced or diametrically opposed, tongues 50.3 extend away from the body of the elbow 50 near to the proximal end 50.1. Each tongue 50.3 has an arcuate undercut 50.2 which is located on an inwardly facing surface 50.4 of the tongue 50.3. The undercuts 50.2 engage with the retaining ring 60. Each finger 50.3 is located at diametrically opposite locations on the elbow 50, and are located on either side of the elbow 50 at the proximal end 50.1 thereof.

[00267] At the ends of the tongues 50.3 there are included finger grips 54. The finger grips 54 enable a user to pull the tongues 50.3 in a radially outward direction relative to the proximal end 50.1, thereby permitting the undercuts 50.2 to clear the rim of retaining ring 60. This then allows the elbow 50 to be disassembled from the mask assembly 10, whereby it can be removed for cleaning. Located near to the finger grips are two undercuts to removably engage with the retaining ring.

[00268] The inside surfaces of the finger grips 54 include a tapered entry way 50.7, whereby when the proximal end 50.1 is pushed into contact with a rim of the retaining ring, the finger grips 54, and thus the undercuts 50.2 are pushed away from the rim of the retaining ring 60, thereby allowing the undercuts to push past the rim, and biased radially inwardly back into engagement, preventing the separation of the proximal end 50.1 from the retaining ring 60..

[00269] An exemplary shape and dimensions of the elbow 50 are indicated in the Figures 30 to 37.

[00270] Illustrated in Figures 10, and Figure 38 to 46 is another elbow 150. The elbow 150 is similar to the elbow 50 described above and like parts have been like numbered. However, the elbow 150 differs from the elbow 50 in that the elbow 150 does not include the moveable tongues 50.3 and finger grips 54 which are included on the elbow 50. Instead, the elbow 150 has six discrete undercuts 50.2 equi-spaced the inner edge 50.5 on the skirt 50.6 which surrounds the proximal end 50.1. In this way the elbow 150 is adapted to be not removable from the shell/cushion 30, 130, 230, 330 and is thus useful for a disposable mask.

[00271] The undercuts 50.2 are formed adjacent the apertures 50.11 through the skirt 50.6. The apertures 50.11 are formed by that portion of the mould which forms the undercut 50.2, preventing molten plastic occupying that space. If desired more or less discrete undercuts 50.2 can be provided.

[00272] The inside surfaces of the skirt 50.6 include a tapered entry way 50.7, whereby when the proximal end 50.1 is pushed into contact with a rim of a retaining ring 60, the skirt 50.6, and thus the undercuts 50.2 are pushed away from the rim of the retaining ring 60, thereby allowing the undercuts 50.2 to push past the rim. The construction of the skirt 50.6 provides a radially inward bias forcing the undercut 50.2 back into engagement once past the rim, thereby preventing the separation of the proximal end 50.1 from the retaining ring 60.

[00273] The elbow can be moulded from any appropriate material such as polycarbonate or polypropylene.

[00274] The elbows 50 and 150 each include a port 56, such as Luer port, to enable access to the interior of the mask shell/cushion. For example, a pressure sensor may be attached. A polypropylene or silicone cap can be used to cover and seal the port when not in use.

[00275] The elbows 50 and 150 can be sized so as to freely rotated when mounted on the mask assembly 10. However, it is preferable that they are not able to freely rotate. Thus while rotation is allowed, when mounted onto a mask assembly 10, the inter-engagement of the components provides as a braking system. This means that, while adjustable, it tends to remain in the position in which it has been set. This is achieved through the combination of sizes shown and the use of one material on the elbow 50 and a different material on the shell/cushion with which it engages. This can be achieved through a slightly interfering fit between the ends of the undercuts 50.2 on the elbow 50 and shell/cushion 30, 130, 230, 330.

[00276] Preferably a suitable combination of materials and component configurations are selected so as to allow the user by hand to easily rotate the elbow to any desired position and once positioned, the elbow 50 or 150 will not move when experiencing the forces which are applied when the mask is attached to the gas conduit and it is in use by a sleeping patient. This allows the user to position the elbow 50 or 150 and thereby the gas conduit relative to the mask and face according to personal preference.

[00277] The elbows 50 and 150 and frame 40 are not directly connected, since their contact is through the shell/cushion 30, 130, 230, 330. Since the shell/cushion is constructed from a flexible material, movement of an air delivery conduit attached to the swivel elbow does not directly disrupt the seal of the shell/cushion. In this way, decoupling of drag forces from the air delivery conduit can be achieved.

[00278] Illustrated in Figures 89 to 98 is a connection piece or elbow 250 which is similar to the elbow 50 and like parts have been like numbered. The elbow 250 differs from the elbow 50 by two prominent features. The first is that the elbow 50 joined direct to a conduit to supply air via the distal end 52. Whereas the elbow 250 provides a groove 250.1 in its distal end 52, so as to receive in the distal end a 180° union 250.2 (see the union 250.2 of Figure 122), which will be rotatably joined, by the annular lip 250.3 on the union 250.2 being received in the

annular groove 250.1. This will provide a swivel connection between the conduit which will supply air, and the elbow 250.

[00279] The second feature of difference is that the elbow 250, as best seen in the cross section of Figure 91, has vent wall 250.4 which extends away from the passage wall 250.5 which directs air flow out of the elbow 250.

[00280] In the vent wall 250.4 is a series of four vent orifices 250.6, which are seen in more detail in cross section of Figure 95. The orifices 250.6 lie at an angle to the outlet direction of air flowing out of the elbow 250. This angle is approximately  $35^\circ$ , or the complementary angle is  $55^\circ$  as is indicated in Figure 90.

[00281] Extending away from the vent wall 250.4 is a divergent housing 250.7. By being divergent, any exhaled gases passing through the vent orifices 250.6 will be readily dispersed.

[00282] Illustrated in Figures 99 to 108, and 122 and 123, is a connection piece or elbow 350, which is similar to the elbow 150 and like parts have been like numbered. The elbow 350 also has the same first and second features or differences described above with respect to the elbows 50 and 250, and accordingly like parts have therewith have also been like numbered.

[00283] The elbow 350, being used to produce a mask assembly predominantly for single use and hospital use, includes a side located and directed Luer port 56. The side mounted Luer port 56 is particularly helpful for the situation where a tube is connected for monitoring purposes. This tube, by being mounted onto the Luer port 56 of the elbow 350, which if it is free to swivel, will mean that there need be no relative twisting of the monitoring tube relative to the supply conduit. This could not happen if the Luer port 56 were on the shell/cushion.

[00284] While the connection pieces or elbows 250 and 350 only have a  $90^\circ$  angle between the inlet at the distal end 52 and the outlet at the proximal end 50.1, it will be readily understood that the connection piece can be constructed with the vent wall 250.4, vent orifices 250.6, and divergent housing 250.7 with any appropriate angle between the inlet at the distal end 52 and the outlet at the proximal end 50.1. This angle can be  $180^\circ$ , whereby an in-line or union connection piece can be produced.

## **§ 6 Retaining ring**

[00285] A retaining ring 60 for use with the mask assembly 10 is shown in Figures 7, 8, 9, 11, and in more detail in Figures 26 to 29. The ring 60 can be manufactured from any appropriate material such as polycarbonate.

[00286] The ring 60 has an outer diameter of approximately 33mm and a thickness of 9mm. Other exemplary dimensions are shown in Figure 27. Figures 8 and 9 show how the retaining ring is positioned in the mask assembly in use.

[00287] Illustrated in the cross sectional views of Figures 8 and 9 and in Figures 26 to 29 it can be seen that the retaining ring 60 comprises a cylinder 62, an annular front flange 64 and a rear flange 66, which between them form an annular groove 67. The rear flange 66 is adapted to be inserted and retained within a complementary shaped channel 524 adjacent the front aperture 30.3 of a shell/cushion 30, 130, 230, 330.

[00288] The front flange 64 provides a square rear surface 65 which forms the front wall of the groove 67. Further the rim 68 of the front flange 64 is bevelled or tapered so that when it enters the tapered entry way on the elbow 50, it will force the undercuts 50.2 to pass thereover.

[00289] It will be noted that the rear flange 66 is symmetrical in shape, while the front flange 64 is not. Further the rear flange 66 is set back from the rear end of the cylinder 62, whereby a cylindrical portion 69 protrudes axially rearwardly away from the rear face of the rear flange 66.

[00290] Illustrated in Figures 118 to 123 is another form of the retaining ring 160 which is similar to the ring 60, and like parts have been like numbered. The ring 160 differs from the ring 60 in that it has a symmetrical configuration so that it can be inserted in either orientation. The front and rear flanges, both marked with numeral 64 are a mirror image of each other and are shaped similarly to the front flange 64 of the ring 60. That is both include a rim 68 which is bevelled or tapered. It will be noted that the ring 160 does not include a rearwardly axially extending cylindrical portion such as is present on the ring 60 as feature 69.

[00291] As can be seen from the cross section of Figure 120, the aperture through the ring 160 has convergent-divergent walls 160.1 and 160.2. These walls are angled or tapered at an angle of 20° so as to assist in the moulding of the ring 160, and to prevent jamming of the proximal end 50.1 of elbows 50 and 250 when these elbows are disconnected from the ring 160.

[00292] The shape of the groove 524 on the shell/cushion to receive the flange 64 of ring 160 is preferably of a complementary shape to allow the ring 160 to provide support.

### **§ 7 Assembly of the components**

[00293] Assembly of Version 1 of a mask system described in chapter § 1 above, will now be described with reference to Figures 7, 8 and 9.

[00294] A frame 40 is pushed into position on the shell/cushion 30 from the front of the shell/cushion 30 and is inserted and engages with the channel 140 on the shell/cushion 30. The retaining ring 60 is adapted to engage with a channel 250 on the shell/cushion 30. The process is similar for the first embodiment.

[00295] Illustrated in the cross sectional views of Figures 8 and 9 of the mask assembly 10, the connection between the elbow 50, retaining ring 60 and shell/cushion 30 is visible. The rear flange 66 of the retaining ring 60 is adapted to be inserted and retained within in the channel 524 adjacent the front aperture 30.3 of a shell/cushion 30.

[00296] The undercut 50.2 on the elbow 50 is adapted to engage with the rear surface 65 of the front flange 64, thus retaining the elbow 50.

[00297] When the proximal end 50.1 passes though the retaining ring 60, seal is formed between a flange or flap 526 on the shell/cushion 30 and the proximal end 32 of the elbow 50. In this way, a leak proof seal, which allows rotation of the elbow 50 relative to the shell/cushion 30 is formed, since the flange or flap 526 extends over the proximal end of the elbow in an annular fashion . This results in a conformable seal between the shell/cushion and elbow.

[00298] Assembly of Version 7 of a mask system described in the § 1 Introduction above, will now be described with reference to Figures 122 to 125.

[00299] Assembly of Version 7 is very similar to that of version 1 described above, except that instead of a single piece frame 40 a two piece frame, made up of pieces 240 and 340 is used, and instead of a shell/cushion 30 with a channel 140 being used a shell/cushion 330 with a peripheral flange 330.1 is used. The assembly of: (a) the frame to the shell/cushion; and (b) the retaining ring and elbow to the shell/cushion; can be done in any order.

[00300] To assemble the frame, a manufacturer will align the rivets 340.1 and spigots 340.7 with the respective holes 330.3 and 330.2, and pass the rivets and spigots through these holes in a rearward to forward direction, starting at the rear of the shell/cushion 330. Once the rivets have been received through the holes 330.2 and the rest of the flange 330.1 is sitting adjacent to front facing surfaces of eh piece 340, then the piece 240 is aligned so

that the apertures 240.1 align with the rivets 340.1, whereby exerting a compressive force on the two pieces 240 and 340 will force the tapered mushroom heads of the rivets 340.1 to pass through the constricted aperture of the apertures 240.1. By appropriately sizing the rivets 340.1 and the apertures 240.1, it may be necessary to compress the flange 330.1 whereby the pieces 240 and 340 will keep the flange 330.1 compressed therebetween once the mushroom head of the rivets are locked into the apertures 240.1. Alternatively, as illustrated in Figure 124, the gap between the pieces 240 and 340 can be sized to receive the flange 330.1 without any compression thereof.

[00301] When the rivets 340.1 are locked into the apertures 240.1, the spigots 340.7 pass through the holes 330.3. The three spigots 340.7 prevent the flange 330.1 from extricating itself from the sandwich formed by the clamping of pieces 240 and 340.

[00302] The assembly of the retaining ring 160 and the elbow 350 onto the aperture 30.3 of the shell/cushion 330 is the same procedure as described above in respect of version 1. As illustrated in Figure 125, the flange 526 can, once the elbow 350 is assembled to the retaining ring 160 and shell/cushions 330, overlie (as illustrated on the right half of figure 125) the rim 32.1 of the proximal end 32 of elbow 350, or as illustrated on the left half of figure 125, the flange 526 can circumferentially seal on the cylindrical outer surface 32.2 adjacent the rims 32.1.

[00303] Described above is a feature of single use mask assemblies where the shell/cushion 30, 130, 230, 330 has a reduced thickness portion to provide a tear point. A single use version is able to be manufactured without such a line of weakness or tear point. Such a single use version, when a single use elbow is used, such as elbows 150 or 350 described above, will allow the shell/cushion 30, 130, 230, 330 (without any reduced thicknesses or tearing points) to separate from the assembled retaining ring 60 or 160 and the elbow 150, or 350, while the elbow 150 or 350 retains the retaining ring 60 or 160 captured thereon. In this way, such a mask assembly will not be able to be reassembled due to the inability to extract or disconnect the retaining ring 60 or 160 from the elbow 150 or 350.

[00304] Although the invention has been described with reference to preferred embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

[00305] It will be understood that the invention disclosed and defined herein extends to all alternative combinations of two or more of the individual features mentioned or evident from the text. All of these different combinations constitute various alternative aspects of the invention.